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10/013,049	12/10/2001	Richard James Riehle	10086/2	2668

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/013,049	RIEHLE ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 34-37* is/are rejected.

7)☒ Claim(s) *26-33, 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the last action is withdrawn in view of the new grounds of rejection set forth below.

Claim Objections

2. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 recites a pH range of "from about 6 to about 8.5". Claim 9 depends from claim 8 which recites a pH range of "from about 7 to about 9". Since the claimed range of claim 9 includes pHs below 7, the claim includes limitations that are not also encompassed by the claim from which it depends and is therefore an improper dependent claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-21 and 34-37 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The additional step of contacting the composition with "at least one microorganism, or at least on enzyme located from the at least one microorganism, in an amount, and at a pH and temperature effective to dehalogenate residual quantities of organically

bound halogen" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 1-21 and 34-37 encompass a treatment process that includes treating a composition containing a wet strength polyamine-epihalohydrin resin comprising a solids content of at least 15 wt% with an enzymatic agent to inhibit, reduce or remove a CPD-forming species. The final amount of CPD-forming species remaining in the composition after the enzyme treatment is defined in terms of the "ACID TEST". That is, the treated composition when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD.

Review of the originally filed disclosure includes 38 Examples.

Example 1 is drawn solely to the manufacture of a wet strength polyamine-epihalohydrin composition with a solids content of 21.08% and includes CPD-forming species.

Example 2 is drawn to an enzymatic treatment of the composition of Example 1. The results of Example 2 do not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See table 1.

Example 3 is drawn to a biodehalogenation treatment of the treated composition of Example 2. It is noted that the treated composition of Example 2 is diluted prior to treatment with the microorganisms. As shown in Table 1 the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD".

Example 4 is drawn to a diluted composition of Example 1. The starting composition has a solids content less than 15 wt%.

Example 5 is drawn to a comparison of a paper product using the treated compositions of Examples 3 and 4.

Examples 6-19 are drawn to enzyme treatments of high solids (at least 15 wt%) wet strength polyamine-epihalohydrin compositions. While a high solids composition was treated with the enzyme composition, the tabulated data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See table 3.

Example 20 is drawn to a combined enzyme-biodehalogenation treatment method of a diluted (less than 15 wt%) starting composition. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD", see table 4, the starting composition did not include a solids composition of at least 15 wt %.

Example 21 is similar to Example 20 but employs twice as much enzyme.

Example 22 is similar to Examples 20 and 21. This example employs a different starting composition but the solids content is still less than 15 wt%.

Example 23 is drawn to biodehalgenation of a starting composition of at least 15 wt%.

Example 24 is drawn to a sequential enzyme-biodehalogenation treatment process with a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD", see table 11, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Example 25 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD", see table 12, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Examples 26-30 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 31 and 32 are drawn to an enzyme treatment of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See tables 21 and 22.

Examples 33 and 34 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Example 35 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See tables 25 and 26.

Example 36 is limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 37 and 38 are drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the

treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See tables 28 and 29.

In summary, only Examples 3, 24 and 25 are drawn to treatment methods that treat a starting composition with a solids content of at least 15 wt% wherein the treatment method includes the claimed enzyme treatment and establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". However, it is apparent to one of ordinary skill in the art that the biodehalogenation step is critical to the invention since each of these examples also included a biodehalogenation step as part of the treatment process that resulted in a treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". Note the examples that were drawn solely to an enzyme treatment of a starting composition of at least 15 wt% did not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-12, 14-16, 18-25 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Richle et al.(US 6,554,961 or US 2003/0205345).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claim 1, the reference of Richle et al. discloses a process for rendering a polyamine-epihalohydrin resin storage stable, that includes treating a composition containing a wet strength polyamine-epihalohydrin resin, the composition comprising a solids content of at least 15 wt% (21%, see Example 75) and including CPD-forming species, with at least one enzymatic agent under conditions to at least one of inhibit, reduce and remove the CPD-forming species to obtain a gelation storage stable reduced CPD-forming resin so that the composition containing the reduced CPD-forming polyamine-epihalohydrin resin when stored for 24 hours at 50degC, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD (See Example 75 and Table 31). With respect to the additional claim limitation that the resin employed in the method "is formed in a reaction having a molar ratio of epihalohydrin to secondary amine group of less that [sic] about 0.50". The reference of Richle et al. discloses employing resins formed in a reaction having a molar ratio from about 0.50 to about 1.8 (See column 13, line 32, to column 14, line 5). The claim language "less than about 0.50" would include "0.50". Note the term

"about" permits some tolerance (See *In re Ayers*, 69 USPQ 109 (CCPA 1946)). As a result, the claim is anticipated by the reference of Richle et al.

With respect to claim 2, see Table 31 that shows CPD ppms of 12.6 and 13.7.

With respect to claims 3 and 4, the enzyme treatment is performed at 40.0 deg. C (See column 89, lines 58-59).

With respect to claims 5 and 6, the enzyme treatment is performed for 6 hours (See column 89, line 62).

With respect to claims 7-9, the enzyme treatment is performed at a pH of 8 (See column 89, line 54).

With respect to claims 10-12, the enzyme treatment is performed using an enzyme to resin ratio of 1:77.

With respect to claims 14-16 and 18, the reference discloses using the enzyme Alcalase (See column 89, line 55).

With respect to claims 19-21, the reference discloses the use of a number of resins (See column 16, lines 33-62).

With respect to the biological dehalogenation of claims 22-25, the reference discloses a subsequent dehalogenation step (See Example 75).

With respect to claim 34, the dehalogenation step meets this claim limitation (See column 17, lines 8-27).

With respect to claims 35 and 36, see Example 76 and 7 which are drawn to paper making steps with the produced product of Example 75.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-13, 19-21 and 34-37 are rejected under 35 U.S.C. 103(a) as being obvious over Bull et al.(US 5,470,742) in view of Miller et al.(US 5,171,795).

With respect to claims 1 and 2, the reference of Bull et al. discloses a method of rendering a polyamine-epihalohydrin resin storage stable. The method discloses treating a composition containing a wet strength polyamine-epihalohydrin resin including a solids content of at least 15 wt% (See column 6, lines 43-48). The composition is treated with at least one enzymatic agent under conditions to at least one of inhibit, reduce and remove CPD-forming species (See column 7, line 40, to column 8, line 37). The final concentration of the CPD-forming species can be as low as 0.1 ppm (See column 11, lines 10-16).

While the reference of Bull et al. discloses treating a resin formed from the reaction of epihalohydrin and a compound including secondary amine groups, the reference is silent as to the molar ratio employed in the reaction. Claim 1 recites that the molar ratio of epihalohydrin to secondary amine group is less than about 0.50.

The reference of Miller et al. discloses that it is known in the art to form polyaminopolyamide-epichlorohydrin resins using molar ratios of epihalohydrin to secondary amine group in the range of 0.05 to 1.5 (See column 4, lines 30-42).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to apply the stabilization treatment process disclosed by the reference of Bull et al. to polyaminopolyamide-epichlorohydrin resins formed using molar ratios of epihalohydrin to secondary amine group below 0.50 for the known and expected result of stabilization of a an art recognized polyaminopolyamide-epichlorohydrin resin using the resin treatment/purification process disclosed by the method of Bull et al.

With respect to claims 3 and 4, the reference of Bull et al. discloses a temperature range of 10-50deg.C.(See column 10, lines 10-13).

With respect to claims 5 and 6, the reference of Bull et al. discloses a time range of 6.5 to 15 hours (See column 11, lines 11-16).

With respect to claims 7-9, the reference of Bull et al. discloses the use of pH ranges from 3-10 (See column 10, lines 14-24).

With respect to claims 10-13, the reference of Bull et al. discloses a range of enzyme concentrations which appears to inherently meet the claim limitations of these claims (See column 10, lines 59-66).

With respect to claims 19-21, the reference of Bull et al. discloses a number of exemplary epichlorohydrin resins (See column 5, line 57, to column 7, line 63).

With respect to claim 34, the disclosed reaction of Bull et al. dehalogenates the halogens bound to the polymer backbone.

With respect to claims 35-37, the reference of Bull et al. discloses making a paper product from the treated composition (See column 12, lines 31-43).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-13 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-13 and 15-20 of U.S. Patent No. 6,552,961 in view of Bull et al.(US 5,470,742) and Miller et al.(US 5,171,795).

Claims 7-13 and 15-20 of U.S. Patent No. 6,554,961 encompass a method of treating a polyamine-epihalohydrin resin composition that includes CPD-forming species and is contacted with a microorganism or enzyme agent to dehalogenate residual quantities of organically bound halogen.

The above claims differ by reciting that the starting composition includes a solids content of at least 15 wt% and includes a CPD-forming species final content of less than 100ppm.

The reference of Bull et al. discloses that it is known in the art to treat a polyamine-epihalohydrin resin composition that includes CPD-forming species and is contacted with a microorganism or enzyme agent to dehalogenate residual quantities of organically bound halogen wherein the solids content can be up to 50 wt% (See column 6, lines 43-48). The reference also teaches that such a treatment results in a CPD-forming species content in the range of 0.1ppm-500ppm (See column 11, lines 1-16).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum solids content based on considerations such as the source of the resin composition and the intended use of the resin composition while providing the benefits associated with the claimed treatment process as evidenced by the reference of Bull et al.

The claims further differ by reciting that the resin employed in the method "is formed in a reaction having a molar ratio of epihalohydrin to secondary amine group of less that [sic] about 0.50".

The reference of Miller et al. discloses that it is known in the art to form polyaminopolyamide-epichlorohydrin resins using molar ratios of epihalohydrin to secondary amine group in the range of 0.05 to 1.5 (See column 4, lines 30-42).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to apply the stabilization treatment process encompassed by the claims of U.S. Patent No. 6,554,961 to polyaminopolyamide-epichlorohydrin resins formed using molar ratios of epihalohydrin to secondary amine group below 0.50 for the known and expected result of stabilization of a an art recognized polyaminopolyamide-epichlorohydrin resin using the resin treatment/purification process encompassed by the patented claims of U.S. Patent No. 6,554,961.

Allowable Subject Matter

13. Claims 26-33 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

While the prior art of record discloses an enzymatic treatment of a composition including polyamine-epihalohydrin resin with a solids content of at least 15 wt% to remove CPD-forming species from the composition (See the reference of Riehle et al. and Bull et al. in view of Miller

et al) and while the prior art further discloses a subsequent biodehalogenation treatment step of the enzyme treated composition (See the reference of Riehle et al.), the prior art of record fails to teach or fairly suggest a treatment process as claimed that includes simultaneously treating the composition with an enzymatic agent to inhibit, reduce or remove CPD-forming resin and an additional enzymatic agent or microorganism to dehalogenate residual quantities of organically bound halogen.

Response to Arguments

15. Applicants' comments filed 1/12/2005, page 3, are persuasive to overcome the rejection of claims 1-2, 14-16, 18-25 and 35-37 over the combination of the references of Riehle et al. and Miller et al. Note a new grounds of rejection has been applied to the under 35 USC 102(e) over the reference of Riehle et al. since the claim limitation "of less than about 0.50" does not preclude "0.50" as a number falling within the claimed range.

16. Applicants' comments filed 1/12/2005, page 4, are persuasive to overcome the provisional obviousness-type double patenting rejections of record.

Note, the terminal disclaimers filed on 1/12/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Applications 10/006,027 and 10/396,155 has been reviewed and are accepted. The terminal disclaimer has been recorded.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB